Analytical Services Division

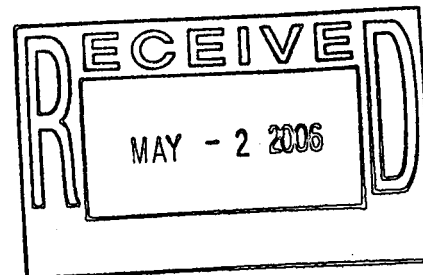Rocky Flats Environmental
Technology Site

GENERAL GUIDELINES
FOR
DATA VERIFICATION AND VALIDATION

DA-GR01-v2

Effective Date: October 1, 2002

Approved: _E A Browski_

Analytical Services

Reviewed For Classification
By: Roger S. Cichorz U/NU
Date: June 4, 2002

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V & V GUIDELINE CHANGE DESCRIPTION FORM

Instructions:	Replace DA-GR01 Version 1 with DA-GR01 Version 2

Guideline: DA-GR01	Version: 2	Originator: E. A. Brovsky

Description: Analytical Services General Guidelines for Verification and Validation.

Section No./Item	Change Description
Cover page	New version and Effective date
V.&V Guideline Change Description Form	The section titled, "Revision History" was replaced with the V&V Guideline Change Description Form.
Introduction	A new introduction was written to incorporate the BOA SOW rather than PSA Modules.
Entire Document	For clarity, change bars appearing on a Section Title indicate changes to the entire Section.
Entire Document	References to the BOA SOW and RFETS BOA Implementation document GR03, are incorporated throughout the document. References to PSA Modules were eliminated. References to Module Specific Verification and Validation (V & V) Guidelines were replaced with Analytical Specific V & V guidelines.
Data Review Checklist	All references to the Data Review Checklist were removed from the Guidelines.
Package Receipt Check	The Package Receipt Check was eliminated from the scope of this guideline. All references to this check were removed.
Data Assessment Program	DA-GR01 was rewritten to incorporate the Data Assessment Program. Therefore, all references to an external document describing this program were eliminated.
Section 2.	Paragraph two of the Section titled, "Determination of Data Verification and Validation Review Levels, Data Qualifiers, And Reason Codes," was reworded for clarity.
Section 2.1, Table2-1	The Data Review Checklist Examination level was eliminated and a review level titled "Data Package Examination" was added.
Section 2.2, Table 2-2	A "U" qualifier was added to the list of Common Data Qualifiers
Section 2.2, Table 2-2	A "JB" qualifier was added to the list of Common Data qualifiers.
Section 2.2.1.1	The "U" and "JB" qualifiers were added to the assigned qualifier hierarchy.
Section 2.3	The section describing Reason Codes was rewritten. The ASD Web Site was identified as the location where reason codes descriptions can be found.
Section 2.3.1	The description and use of Reason Codes were rewritten.
Section 3.1	The Data Review Checklist Examination level was eliminated and a review level titled "Data Package Examination" was added.
Section 3.2	Data Review Checklist Examination, and Partial and Complete Data Verification were eliminated. These three sections were replaced with the Data Package Verification section .
3.3	The Data Validation section was rewritten.
N/A	Data Review Checklist (DRC) Examination Instructions were eliminated.
4.	The section titled, "Verification and Validation Step" was eliminated and the Section titled "Verification and Validation Process" was added.
4.1	The section titled, "Overview of Verification and Validation Process was replaced with a section titled, "General Information for V & V Activities".

V & V GUIDELINE CHANGE DESCRIPTION FORM (continued)

Section No./Item	Change Description
4.2	The section titled, "General Instructions for package Verification was replaced with a section titled, "Data Verification Process".
4.3	The section titled, "General Instructions for package Validation was replaced with a section titled, "Data Validation Process".
5.	A section titled, "Examination Instructions" was added.
6.	The section titled, "Verification and Validation Instructions was updated to reflect the elimination of the DRC Checklist, and the requirements of the new source documents, GR03 and the BOA Statement of Work.
7.	The section titled, "Completion of the Data Assessment Record" was rewritten.
8.	Section 8, "References," was updated.

1.   INTRODUCTION

Analytical Services General Guidelines for Data Verification and Validation, DA-GR01, identifies the Analytical Services Division's (ASD) overall Data Assessment Process, and the methodologies used to perform Sample Data Package reviews. In addition, this document provides general verification and validation guidelines common to all Sample Data Packages generated under the National Basic Ordering Agreement (BOA) Statement of Work (SOW) and the Rocky Flats Environmental Technology Site (Site) BOA Implementation Requirements documents, GR03 & GR04.

This document is to be used in conjunction with Analytical Specific Verification and Validation (V & V) Guidelines that include but not limited to the following:

- DA-SS01 Verification and Validation Guidelines for Volatile Organics Analyses
- DA-SS02 Verification and Validation Guidelines for Semivolatile Organics Analyses
- DA-SS03 Verification and Validation Guidelines for PCB/Pesticides Analyses
- DA-SS05 Verification and Validation Guidelines for Inorganics Analysis
- DA-SS06 Verification and Validation Guidelines for Water Quality Parameters Analyses
- DA-SS08 Verification and Validation Guidelines for Waste Characteristics Analyses
- DA-RC01 Verification and Validation Guidelines for Isotopic Determinations by Alpha Spectrometry
- DA-RC02 Verification and Validation Guidelines for Tritium Analysis by Liquid Scintillation Counting
- DA-RC04 Verification and Validation Guidelines for Gross Alpha and Gross Beta by Gas Flow Proportional Counting
- DA-RC05 Verification and Validation Guidelines for Radiometric Strontium by Gas Proportional Counting
- DA-GAM Verification and Validation Guidelines for Radionuclides by Gamma Spectrometry

Instructions contained in Analytical Specific V & V Guidelines shall supersede the General Guidelines For Data Verification And Validation.

The data assessment program outlined in this document has been developed to assess the usability of data and to monitor laboratory performance. The verification and validation process provides data users with information on the quality of data prior to its use and at the same time promotes an environment that continually improves data quality. Laboratories are provided copies of data assessment reports on all validated data as a means of providing feedback on their ability to produce a quality product that meets all subcontract requirements. In addition, this program provides ASD with the information necessary to direct analytical work to laboratories with superior performance thereby providing data users with timely, high quality data.

The General Guidelines for Data V & V address the process and terminology used to assess data at the examination, verification and validation levels. This is accomplished through the evaluation of laboratory quality control indicators, laboratory adherence to standard methods, and laboratory documentation requirements. This guideline does not address the use of field duplicates, field blanks, trip blanks, and equipment blanks in evaluating the overall quality of sample results. The frequency of field quality control samples and the process used to evaluate the impact of field quality control results on overall assessment of the data are determined according to individual Project requirements. The specification and assessment of field QC samples are performed by the Project and not by Analytical Services Division.

2. DETERMINATION OF DATA VERIFICATION AND VALIDATION REVIEW LEVELS, DATA QUALIFIERS, AND REASON CODES

All analytical data generated in conjunction with the BOA and Site Specific BOA Implementation Documents are subject to data assessment through data examination and data verification or validation. The results of the data assessment process as well as the level of the assessment are documented using the following designations:

- Review Levels
- Data Qualifiers
- Reason Codes

These three designations provide the data user with information regarding the quality associated with individual data points, the depth to which the data was interrogated, and a coded description of the specifics that lead the qualification of the data.

2.1. Review Levels

The three levels of data assessment review are identified in Table 2-1 below. For electronic data, the data review level is indicated by the character immediately following the data qualifier. A "1" following the qualifier indicates verification was performed, a "blank" following the qualifier indicates validation was performed. Data is not qualified at the Examination Level. Data assessment review levels are further described in Section 3 of this document.

TABLE 2-1 DATA QUALITY ASSESSMENT REVIEW LEVELS

Review Level Designator	Example Data Qualifier	Review Level Description
N/A	N/A	Data Package Examination
1	J1	Data Verification
Blank	V	Data Validation

2.2. Data Qualifiers

Data qualifiers are assigned to individual data points to describe the level of quality associated with specific data points. The common data qualifiers in use are V, J, U, JB, NJ, UJ, and R. Table 2-2 provides a brief description of the general data qualifiers assigned to results in the data review process. Additional data qualifiers may be defined in Analytical Specific V & V Guidelines.

Table 2-2 Common Data Qualifiers

Qualifier	Description
V	No problems with the data were observed at the indicated review level.
J	The associated value is an estimated quantity.
U	The associated value is considered undetected at an elevated level of detection
JB	Qualified due to blank contamination (Results Below RDL)
NJ	The associated value is presumptively estimated
UJ	The associated value is considered estimated at an elevated level of detection
R	The data are unusable. (Note: Analyte may or may not be present.)

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2.2.1. **Application**: All data are considered valid, "V", unless the data assessment process identifies problems that warrant the data to be qualified otherwise.

2.2.1.1. Multiple data qualifiers may be identified for an individual data point. When this occurs, one data qualifier flag will be assigned according to the following hierarchy:
- R
- NJ
- UJ
- U
- JB
- J
- V

2.3. Reason Codes

Reason codes are three-digit designators that accompany all J, JB, U, UJ, NJ and R qualifiers as a means of providing an explanation for electronically qualified data. In addition, some V-qualified data may also include reason codes that provide information not related to the quality of the data. A table containing a list of Reason Codes and their associated descriptions are maintained on the ASD Web Site.

2.3.1. Reason codes are used to provide a brief explanation for the cause of data qualification or are used to identify laboratory subcontract noncompliance during the generation of such data. Reason codes applied for subcontract noncompliance are usually applied at the data package level (i.e., the reason code is assigned to all data points) and usually do not affect data quality.

2.4. Data Qualifier Format

The format for qualifying data includes the qualifier letter(s), the review level (1, or blank) followed by one or more three-digit reason code(s) if applicable. For example, the rating **[R1 101]**, indicates that verification was performed on the data, the data were rejected, and the reason code for the rejection is 101.

3. OVERVIEW OF REVIEW LEVELS

The data assessment process includes the following levels of data review:
- Data Package Examination
- Package Verification
- Data Validation

3.1. Data Package Examination

A Data Package Examination is performed on 100% of all Sample Data Packages upon the receipt of requested data package components. Data Package Examination is the minimum data assessment level and is performed on each data package generated under the BOA Statement of Work. The Data Package Examination is completed by ASD personnel or subcontracted employees.

3.1.1. The primary objective of the Data Package Examination is to perform a cursory assessment of the data package to identify gross reporting errors and to assess the

laboratory's evaluation of their data as described in the sample case narrative. This assessment is performed prior to preliminary release of data pending a verification or validation.

3.1.2. Data qualifiers will not be assigned based on Data Package Examination. Data packages assessed at the examination level and determined to contain problems affecting data quality will either be returned to the laboratory for correction or will require a data verification or validation prior to preliminary release of the data.

3.2. Data Package Verification

Data Package Verification consists of an evaluation of the sample data package summary forms to determine the extent to which the subcontract laboratory met method and subcontract specific quality control and reporting criteria.

3.2.1. Verification is scheduled (by ASD) through the Analytical Services Tool Kit (AST) sample management application. This application allows ASD to set the percentage of Sample Data Packages subject to complete verification as a means of monitoring laboratory performance. The percentage may very depending on a laboratory's ability to submit contractually compliant data packages with acceptable levels of data quality.

3.2.2. Verification rates may also be altered according to program requirements for a specific project.

3.2.3. Verification will be completed in accordance with all of the verification steps identified in Section 6 of this document and all of the verification activities identified in the applicable Analytical Specific Verification and Validation Guidelines. Verification for a data package must be completed within 7 calendar days from the date of request.

3.2.4. Verification data qualifiers with reason codes will be applied to electronic sample data results as part of the verification process.

3.3. Data Package Validation

The data validation process is designed to determine data quality and the extent to which the subcontract laboratory, accurately and completely, reported all sample and quality control results, and their adherence to subcontract requirements.

3.3.1. Data validation will be performed on packages when:

- Scheduled through AST at a frequency established by ASD to monitor laboratory performance. In general, approximately 25% of sample data packages will be validated for a given laboratory and analytical type, e.g., VOA, Metals, Alpha Spec. etc..
- ASD selects additional packages for a given laboratory based on the results of other verifications or validations.
- Client program or project requirements.

3.3.2. Data validation may be performed by ASD personnel or by an independent validation subcontractor.

3.3.3. Data validation activities will be completed in accordance with all of the verification and validation steps identified in Section 6 of this document as well as

all of the verification and validation activities identified in the applicable Analytical Specific V & V Guidelines.

3.3.4. Routine validation reports must be completed within 30 calendar days from the date of request. Expedited validation will be handled on a case by case basis.

3.3.5. Validation data qualifiers with reason codes will be applied to electronic sample data results as part of the validation process.

3.3.6. If validation is performed on a sample data package that was previously assessed at the verification level, all verification qualifiers (e.g. V1, U1 etc.) shall be replace with the appropriate validation qualifier (e.g. V, U, etc.).

4. VERIFICATION AND VALIDATION PROCESS

4.1. General Information for V & V Activities

The verification and validation criteria contained within this section are to be used in conjunction with the appropriate Analytical Specific V & V Guideline.

4.1.1. Data evaluation results may include:

4.1.1.1. Errors or omissions for which corrections or additional information will be requested.

4.1.1.2. Errors or omissions for which corrections and additional information will not be requested but will be recorded as part of the lab evaluation/continuous improvement program.

4.1.2. All verification and validation results will be documented on a Data Quality Assessment Report. An example Data Quality Assessment Report is presented as Attachment 1 of this Guideline.

4.1.3. Analytical Specific Verification and Validation Guidelines may include some or all verification or validation assessments by reference to other documents. For example, all items in the QA Summary section may refer to published EPA data assessment guidelines.

4.1.4. Characters enclosed by square brackets, [ ], indicate data qualifiers and reason codes to be assigned if evaluation indicates non-compliance to the evaluation item. If the non-compliance affects data quality, this code will include two parts: the data qualifier letter and the 3-digit reason code (e.g. **[J 545]**). If non-compliance does not involve a change in the data qualification status then the data qualifier will include only the reason code portion (e.g. **[545]**).

   Note: Verification and Validation Instructions contained in DA-GR01 and in Analytical Specific V & V Guidelines provide data qualifiers without Review Level Designation. The appropriate Review Level Designator is added to the data qualifier when applied to electronic data only.

4.1.5. Non-compliant items may require corrective actions by the subcontracted laboratory to rectify problems with a specific sample data package or to prevent the problem from occurring in subsequent sample data packages. When these

situations occur, ASD or their subcontractor shall issue a Non-Compliance Notification. An example Non-Conformance Notification is provided as Attachment 2 of this guideline.

4.1.6. The format for verification and validation guidelines are as follows:

Review Items: Lists the deliverable sections of the Sample Data Package which will be needed for the review step.

Objective: Includes a brief description of the goals for this evaluation.

Source: Lists reference locations for requirements applicable to this evaluation.

Evaluation: Identifies the verification and validation activities to be performed for each data review item. In most cases data validation includes review steps that exceed those required for verification.

4.2. Data Verification Process

The sample data package verification process begins with the review of all applicable verification items as specified in DA-GR01 and in Analytical Specific V & V guidelines. Data verification is completed with the execution of the following process steps as applicable:

4.2.1. The completion of a Data Quality Assessment Report (DQA) for each Sample Data Package verified. The report shall document all problems related to data quality, and identify errors, omissions, reason codes, and data qualifiers for all verification steps identified in the General Guidelines for Data Verification and Validation (DA-GR01), and in appropriate Analytical Specific V & V Guidelines.

4.2.2. The completion of a Non-Compliance Notification (NCN) to correct errors, problems related to data quality, omissions, and nonconformances to contract requirements. The DQA Report shall reference all NCNs issued. An example NCN Report is provided in Attachment 2.

4.2.3. If the verification process identifies a potential for problems that cannot be fully assessed at the verification level, then the assessor shall recommend the assessment continue at the validation level

4.2.4. The upload of electronic V & V Qualifiers and reason codes to the Electronic Data Deliverable (EDD).

4.2.5. A cursory comparison of the sample results on the hardcopy Data Package against the results in the EDD.

4.3. Data Validation Process

The Sample data package Validation process begins with the review of all applicable verification and validation items as specified in DA-GR01 and in Analytical Specific V & V guidelines. Data validation is completed with the execution of the following process steps as applicable:

4.3.1. The completion of a DQA Report for each Sample Data Package validated. The report shall document all problems related to data quality, and identify errors, omissions, reason codes, and data qualifiers for all data assessment steps

identified in DA-GR01, and in appropriate Analytical Specific V & V Guidelines.

4.3.2. The completion of a NCN to correct errors, problems related to data quality, omissions, and nonconformances to contract requirements. The DQA Report shall reference all NCNs issued.

4.3.3. The examination of raw data to ensure all information reported on data package summary forms is supported.

4.3.4. The upload of electronic V & V Qualifiers and reason codes to the Electronic Data Deliverable (EDD).

4.3.5. A comprehensive comparison of all sample results on the hardcopy Data Package against the results in the EDD.

5. EXAMINATION INSTRUCTIONS

The following sample data package assessment activities apply to Examination only. A more detailed look at the items addressed in this section are contained in Analytical Specific Verification and Validation Instructions.

5.1. **Sample Data Package (SDP) Narrative**

Review Items:	SDP Narrative
Objective:	To determine if the SDP narrative contains information that warrants a data verification or validation prior to the preliminary release of the data.
Source:	BOA Attachment 1, § 3.1.6.2
Evaluation:	*The following step applies to examination only.*
Item 1:	Review the SDP narrative for problems that may have an adverse affect on data quality or sample integrity. This may include but not limited to problems associated with: instrument calibration, blank or reagent contamination, QC samples, holding time, or sample handling.
Action 1a:	Use professional judgement to determine if the problems identified in the SDP narrative have potential to affect data quality. Problems that have potential to affect data quality should be verified or validated prior to data release.
Action 1b:	Use professional judgement to recommend an appropriate review level (Verification or Validation) as applicable.

6. VERIFICATION AND VALIDATION INSTRUCTIONS

The sample data package assessment activities in the following subsections are common to all sample data packages. The instructions included in this section are to be used in conjunction with the Analytical Specific V & V Guidelines applicable to the Sample Data Package.

6.1. Sample Data Package Cover Page

Review Items: SDP Cover Page

Objective: To verify the SDP Cover Page information is complete and correct.

Source: GR03 § 2.4; and Attachment I to BOA Attachment 1.

Evaluation: *The following steps apply to both verification and validation.*

Item 1: Verify that the cover page is the first page of the Sample Data Package and contains, at a minimum, the following information:

- Laboratory Name,
- Subcontract Number,
- Statement of Work Identifier,
- Method Name or Description,
- Report Identification Number(RIN),
- Laboratory Report Identification Number (ID),
- Line Item Codes associated with the RIN,
- Contractor Sample Numbers cross-referenced to Laboratory ID Numbers.
- Date Samples received at Laboratory
- Certification Statement followed by Name of Laboratory Manager or Designee, Title, & Date
- Invoice Statement

Action 1: If any of this information is missing or incomplete, include a comment in the Data Quality Assessment Report, assign the reason code [804] for all data, and issue a Non-Conformance Notification (NCN) requesting resubmittal of the Electronic Image Data Package (E-Image) with a corrected cover page.

6.2. Sample Data Package (SDP)

Review Items: All SDP Deliverable Components

Objective: To determine if overall composition of component deliverables are in compliance to requirements.

Source: GR03 § 2.4; BOA Attachment 1, §3.4; and Attachment I to BOA Attachment 1.

Evaluation: *The following steps apply to both verification and validation.*

Item 1: Determine if all SDP deliverable sections are present.

Action 1: If a SDP deliverable section is missing issue a Non Compliance Notification for the missing components and assign the reason code **[801]**.

Item 2: Determine if the sample data package consecutively paginated by examining at least ten sheets for increasing page numbers.

Action 2: If problems with pagination are found, issue a NCN requesting a corrected data package, comment and assign the reason code, **[804]**.

Evaluation: *The following steps apply to validation only.*

Item 3: Determine if SDP required items are referenced in other SDPs.

Action 3a: If required items, not critical to verification or validation, are referenced in another SDP, comment, issue a NCN for missing documentation and assign the reason code **[802]**.

Action 3b: If required items that are critical to verification or validation are referenced in another SDP, comment and issue a NCN for missing documentation. Assign the reason code **[801]**.

Item 4: Determine if color paper is used in any hardcopy documents.

Action 4: If hardcopy documents contain colored paper, comment and issue a NCN to prevent recurrence. Assign reason code **[804]**.

Item 5: Determine if Non-Site samples are reported with Site Samples.

Action 5: If Non Site samples are reported with Site samples, comment in the DQA Report, and issue a NCN to prevent recurrence. Assign the reason code **[809]**.

6.3. **Chain of Custody (COC), Holding Times, and Sample Preservation**

Review Items: COC, Laboratory Sample Receiving Documentation, Cover Page Comments, Sample Case Narrative, raw data, data summary forms

Objective: To ascertain the validity of results based on the holding time and preservation of the sample and to verify the COC, and Sample Receiving documentation are included in the SDP.

Source: GR03 § 2.4.2, BOA Attachment 1, § 3.1.2.

Evaluation: *The following steps apply to both verification and validation.*

Item 1: Verify that COCs are included for all samples listed on the Cover Page of the SDP.

Action 1a: If COCs are not included for all samples, initiate a NCN for the missing documentation and assign the reason code **[801]**

Action 1b: If COC records were not generated for a sample, qualify the sample as rejected and assign the reason code **[R 218]**.

Item 2: Verify the continuity of each sample's custody is evidenced on the chain of custody with the dates, times, and signatures of each transaction from sampling to final disposition. This continuity is verified through the following specific items:

◊ All documents accompanying the samples were signed and dated (including time) by the sample custodian at the time of sample shipment and by the lab sample custodian or alternate at time of sample receipt.

◊ Verification that the following were recorded by the sample custodian (or alternate) on COC forms, in the sample log, or on preprinted sample log-in sheets.

- Condition of the shipping container
- Presence or absence and condition of custody seals on shipping and/or sample containers
- Custody seal numbers, when present
- Presence or absence of airbills or airbill stickers
- Airbill or airbill sticker numbers
- Presence or absence of Site custody records
- Presence or absence of Site packing lists
- Verification of agreement or non-agreement of information recorded on shipping documents and sample containers
- Temperature of shipping container, if appropriate
- pH of the samples, when appropriate
- Problems or discrepancies.

Action 2a: If SDP contains insufficient documentation to verify sample custody continuity, issue a Non Compliance Notification for the missing documentation and assign the reason code **[803]**.

Action 2b: If the COC continuity was corrupted, determine if the Laboratory Contractor Technical Representative (CTR), or the QA Record File for this SDP has documentation addressing this issue. Any non-conformances are documented for inclusion into a NCN.

- If appropriate documentation indicates the laboratory was not responsible for the corruption of the COC continuity, and the custody of the samples cannot be verified, qualify affected results as rejected and assign the reason code **[R 704]**.

- If appropriate documentation is not available and the custody of the samples cannot be verified, qualify affected results as rejected and assign the reason code **[R 218]**.

Action 2c If documentation of preservation checks are not present, issue a NCN requesting the information, comment and assign the reason code **[804]**.

Item 3: Verify that the COC documented preservation is consistent with preservation requirements of the applicable Analytical Specific V & V Guidelines.

Action 3: If preservation is non-compliant, at a minimum, comment and assign the reason code **[703]**, otherwise, use professional judgement to qualify the data.

Item 4: Calculate actual holding times by comparing the sampling date on the Site COC with dates of analysis found in the laboratory raw data or data summary forms.

Action 4: Apply the appropriate holding time criteria and actions given in the Analytical Specific V & V Guidelines.

Item 5: Determine if samples were properly preserved prior to analysis.

Action 5: If documentation indicates samples were not properly preserved prior to analysis, apply the appropriate actions from the Analytical Specific V & V Guidelines.

6.4. **Electronic Data Deliverable (EDD)**

Review Items: SDP Deliverable Components, EDD

Objective: To ensure that electronically-reported data are accurate.

Sources: GR03 § 2.4; GR03 Appendix A, BOA Attachment 1, §3.4; and Attachment I to BOA Attachment 1.

Evaluation: *The following step applies to verification only.*

Item 1:   Determine if EDD sample results accurately reflect the data contained in the SDP by verifying 5 random analyte results from the EDD against those on the SDP sample results summary (Form 1 or equivalent).

Action 1:   If discrepancies are found, initiate a NCN to obtain corrections to the problems associated with the EDD and/or Sample Data Package.. Assign the reason code **[803]**. Do not complete the DQA Report until a corrected EDD and/or SDP are received and verified to be accurate.

Evaluation: *The following step applies to validation only.*

Item 2:   Determine if EDD sample results accurately reflect the data contained in the SDP by verifying all analyte results from the EDD against those on the SDP sample results summary (Form 1 or equivalent).

Action 2:   If there are any discrepancies found, initiate a Non-Compliance If discrepancies are found, initiate a NCN to obtain corrections to the problems associated with the EDD and/or Sample Data Package.. Assign the reason code **[803]**. Do not complete the DQA Report until a corrected EDD and/or SDP are received and verified to be accurate.

6.5. **Analytical Specific V & V Guidelines**

Complete the data review by evaluating the appropriate items in the Analytical Specific V & V Guidelines.

7.   COMPLETION OF THE DATA ASSESSMENT RECORD

All verification and validation activities must include a completed Data Quality Assessment (DQA) Report. The DQA report contains four sections, a header, a block information section, a section containing data assessment results, and a footer. An example of a completed Data Quality Assessment Report for a metals SDP is included as Attachment 1 of this guideline.

7.1. **DQA Report Header**

The DQA Report Header shall appear on all pages and contain the character portion of the Analytical Line Item Code (LIC), the title, "Data Quality Assessment Report", and "Rocky Flats Environmental Technology Site" (see Appendix 1 for an example DQA Report Header).

7.2. **Block Information Section**

At a minimum, the Block Information Section shall contain the following information:
- Report Identification Number (RIN)
- Analytical Method/Analytical Specific Line Item Code(s)
- Full Analytical Laboratory Name

- Laboratory Sample Delivery Group (SDG) or Analytical Batch ID
- Review Level (Verification or Validation)
- Entity performing the Data Assessment
- Data Assessment Guideline Identifier(s) and Revision Number
- Number of Samples
- An Analytical Specific list of Quality Control Items. Each item shall indicated whether or not it was reviewed and shall include references to applicable Actions or Comments.

> **Note:** Each Analytical Specific V & V guideline will include a unique list of Quality Control Items. Listed items may or may not be applicable to verification, but all items shall be reviewed for validation.

7.3.   Data Assessment Results

Data assessment results are presented in three sections, 1) A preface describing how to interpret the DQA Report, 2) Action Items describing technical non-compliances that result in the qualification of analytical data; 3) Comments describing technical or contractual non-compliances that do not result in the qualification of data.

7.3.1.   *Preface:* The preface shall contain a brief explanation of the report layout, and a description of the data qualifiers and how they are used. The following is an example of a preface to the data assessment results:

> *Data Assessment results are classified as either Action Items or Comments. Action Items are technical non-compliances that result in qualification of analytical results. Data may be qualified as valid (V), estimated (J), presumptively estimated (NJ), estimated at an elevated level of detection (UJ), or rejected (R). Multiple qualifiers may be associated with any given data point based on the number of problems identified, however, the assigned qualifier is based upon the following hierarchy: R, UJ, NJ, J, V. All data points that are not qualified based upon action items in this report are considered valid (V). Comments are technical non-compliances or contractual non-compliances that do not result in qualification of data.*

7.3.2.   *Action Items*: This section contains a numbered list of technical non-compliances that result in the qualification of data. Each numbered item contains a description of the non-compliance, identification of data affected by the non-compliance, a data qualifier and reason code, and a NCN identifier as applicable.

7.3.3.   *Comments:* This section contains a description of technical or contractual non-compliances that do not result in the qualification of data. If the non-compliance results in the issuance of a NCN, the NCN identifier shall be provided.

7.4.   DQA Report Footer

The DQA Report footer shall appear on all pages and contain the following at a minimum, DQA Electronic Report File name/Reviewers initials, page number, and report date. The file name shall be in the following format:

YYA####lic-c# (e.g.,02N0165voa-e1)

where

YYA####	=	Report Identification Number (RIN)
lic	=	The three character alpha prefix of the Line Item Code(RIN)*
c	=	Indicates the assessment level performed (i.e., "e" identifies verification, and "a" indicates validation).

\# = Report number identifier. Used to uniquely identify multiple reports with the same RIN and alpha prefix.

* The alpha prefix, "WCH" shall be used in the DQA electronic report file name for LICs beginning with "WCH" or "MIS".

7.5. Verification Documentation

Documentation for data assessment performed at the verification level consists of a completed DQA Report and copies of applicable NCNs associated with the assessment. If an Electronic Data Deliverable (EDD) is not available, data summary form(s) annotated with data assessment qualifiers and reason codes shall be included with the DQA Report.

7.6. Validation Documentation

Documentation for data assessment performed at the verification level consists of a completed DQA Report, validation worksheets or other related documentation, and copies of applicable NCNs associated with the assessment. If an Electronic Data Deliverable (EDD) is not available, data summary form(s) annotated with data assessment qualifiers and reason codes shall be included with the DQA Report.

7.7. Application of E-Qualifiers and Reason Codes to EDD

Upon completion of Data Quality Assessment Reports, data qualifiers and reason codes shall be applied to the EDD using an electronic application.

8. REFERENCES

The following references were either used to develop DA-GR01 or were cited somewhere within the document:

- Guidance for Radiochemical Data Validation, Draft RD4, October 4, 1995, prepared by Office of Transportation, Emergency Management & Analytical Services (EM 26), Office of Compliance and Program Coordination, Environmental Management, U.S. Department of Energy.
- Reason Codes for Data Assessment, Analytical Services Document
- RFETS BOA Implementation Requirements, GR03 Version A.5
- RFETS BOA Implementation Requirements, GR04 Version A
- Basic Ordering Agreement (BOA) for Laboratory Analytical Services administered by Westinghouse Savannah River Company on behalf of the Department of Energy.

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ATTACHMENT 1: DATA QUALITY ASSESSMENT REPORT EXAMPLE

MET
Data Quality Assessment Report
Rocky Flats Environmental Technology Site

RIN Number	Analytical Method/Analytical Specific Line Item Code	Review Level
02N0165	Total Metals including Mercury / MET-A-021	Verification

Analytical Laboratory	Assessment Performed by	Data Assessment Guideline Identifiers	Number of Samples
Best Laboratory (SDG: 12345)	DataSess Inc.	DA-GR01 v2, DA-SS05 v3	6/A021

Sample Numbers: 02N0165-001.001, 02N0165-002.001, 02N0165-003.001, 02N0165-004.001, 02N0165-005.001, 02N0165-006.001

Quality Control Item	Reviewed (Y or N)	Non-Compliance Identified
General (Cover Page, General SDP Requirements Narrative)	Y	N
Chain of Custody, Preservation, and Holdings	Y	N
Sample Results	Y	N
Calibration Verification, CRDL Standard	Y	Action Item 1
Verification and Preparation Blanks	Y	Action Item 2
Interference Check Sample	Y	N
Matrix Spike	Y	Action Item 3, 4 Comment 1
Duplicates	Y	Action Item 5 Comment 2
Laboratory Control Sample	Y	Action Item 6
Standard Additions	NA	N
ICP Serial Dilution	Y	Action Item 7
Instrument Detection Limit	Y	N
Other: Interelement Correction Factors, Linear Range Studies, Preparation Logs, Instrument Run Log	Y	N
Preparation and Instrument RAW Data	N	N
Standards	N	N
EDD	Y	N

Y   Item was reviewed or non-compliance was identified

N   Item was not reviewed or non-compliance was not identified

N/A   Item is not applicable to the Line Item

MET

Data Quality Assessment Report
Rocky Flats Environmental Technology Site

Data Assessment results are classified as either Action Items or Comments. Action Items are technical non-compliances that result in qualification of analytical results. Data may be qualified as valid (V), estimated (J), presumptively estimated (NJ), estimated at an elevated level of detection (UJ), or rejected (R). Multiple qualifiers may be associated with any given data point based on the number of problems identified, however, the assigned qualifier is based upon the following hierarchy: R, UJ, NJ, J, V. All data points that are not qualified based upon action items in this report are considered valid (V). Comments are technical non-compliances or contractual non-compliances that do not result in qualification of data.

Action Items:

1. The following sample results failed the CRDL QC criteria of 80-120%, with a %R greater than 120%, or between 40-79%. Sample results less than 3X the RDL are estimated (J):

   - Arsenic in all six samples. [J 105]

2. The following sample results are qualified as estimated (UJ) because the calibration or preparation blanks exceeded the IDL and the sample concentration was less than five times (5X) the blank concentration:

   - Tin, and thallium in all six samples. [UJ 107]

3. The following sample results are qualified as estimated (J) because the matrix spike recoveries were below the QC limits of 75-125%:

   - Antimony, manganese, and titanium in all six samples. [J 112]

4. The following detected sample results are qualified as estimated (J) because the matrix spike recoveries failed the QC limits of 75-125%, and was below 30%:

   - Silica in all six samples. [J 113]

5. The following sample results are qualified as estimated (J) because the duplicate QC limit of 35 %RPD for solid samples was exceeded:

   - Chromium in all six samples. [J 111]

6. The following sample results are qualified as rejected (R) because the LCS QC limit of 80-120 %R was not met:

   - Silica in all six samples. [R 110]

7. The following sample results were qualified as estimated (J) because the serial dilution %Ds exceeded the acceptance criteria of 10%, and the initial sample result was greater than 50X IDL:

   - Manganese, and titanium in all six samples. [J 117]

Comments:

1. Aluminum, calcium, iron, magnesium, manganese, silver, vanadium, and mercury were flagged for not meeting the matrix spike QC criteria. The values were within the guidelines criteria of 75-125 %R, or not applicable, so no action was taken.
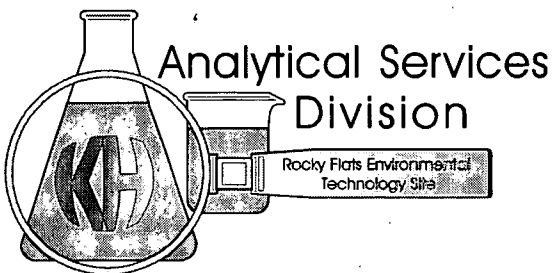
Verification/Validation Signature_____   Date:_____

Reviewer Signature_____   Date:_____
   (*Validation only*)

ATTACHMENT 2: NON-COMPLIANCE NOTIFICATION EXAMPLE

Analytical Services Division

Rocky Flats Environmental Technology Site

Non-Compliance Notification

Non- Compliance Notification Number: NCNR02-045   **Date Issued:** 2/19/02

To: Betty Best   **From :** Jane Doe

Best Laboratory   CTR, Kaiser-Hill Analytical Services

303-555-1234   303-966-0514

Problem: NCNR02-045.001   **Response Due By:** 2/19/02

Explanation: Raw data for the initial calibration (10ug/l) standard analyzed on 1/2/02 at 10:58 is missing. Applies to two RIN's, 02D0406, and 02S0057.

Source Requirements: BOA, Attachment 1, section 3
GR03-A.3, section 1.4.4

Required Actions: Please submit missing data

Affected RINs and Line Item Codes:

RIN	LINE ITEM CODE
02D0406	VOA-A-007